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Supplementary data

Table S1. Quantile regression for maximum procedural anxiety

Model specification	Quantile (tau)	VR coefficient (95% CI)*	P value
Adjusted for baseline VASa	0.50	0.40 (-1.21 to 2.01)	0.627
Adjusted for baseline VASa	0.75	0.25 (-2.07 to 2.57)	0.834
Additionally adjusted for morphine and midazolam dose	0.50	0.40 (-1.34 to 2.14)	0.654
Additionally adjusted for morphine and midazolam dose	0.75	-0.40 (-2.16 to 1.36)	0.658

* 95% CIs for quantile regression are approximate (estimate ± 1.96 × bootstrap SE). Estimates are expressed as VR minus control; negative values indicate lower anxiety with VR.

Table S2. Impact of VR on Maximum Procedural Anxiety: Sensitivity Analyses

Model Specification	Adjusted difference (95% CI)*	P Value	Covariates included in model
Model 1 (Primary Adjusted)	-0.21 (-1.55 to 1.14)	0.759	Baseline anxiety
Model 2 (Pharmacologic)	-0.25 (-1.60 to 1.09)	0.706	Baseline anxiety, Total Morphine dose, Total Midazolam dose
Model 3 (Complexity)	-0.40 (-1.81 to 1.02)	0.576	Baseline anxiety, J-CTO Score

*Adjusted differences are expressed as VR minus usual care and were obtained from linear regression models (ANCOVA framework) as specified.

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Table S3. Exploratory analyses by baseline anxiety thresholds

Analysis specification	**Estimate (95% CI)**	**P value**	**Model details**
Interaction term: baseline VASa > = 5	-1.79 (-4.53 to 0.95)	0.196	Linear model with baseline VASa, high baseline indicator, and interaction
Stratum: baseline VASa < 5	0.64 (-1.21 to 2.49)	0.486	Within-stratum ANCOVA adjusted for baseline VASa
Stratum: baseline VASa > = 5	-1.11 (-3.28 to 1.05)	0.299	Within-stratum ANCOVA adjusted for baseline VASa
Interaction term: baseline VASa > = 7	-1.08 (-4.19 to 2.04)	0.490	Linear model with baseline VASa, high baseline indicator, and interaction
Stratum: baseline VASa < 7	0.14 (-1.40 to 1.68)	0.855	Within-stratum ANCOVA adjusted for baseline VASa
Stratum: baseline VASa > = 7	-1.90 (-4.99 to 1.19)	0.206	Within-stratum ANCOVA adjusted for baseline VASa

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CONSORT 2025 checklist

Section/topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured	1a	Identification as a randomised trial	Title Page ("...randomized... ReViCTO trial")
abstract	1b	Structured summary of the trial design, methods, results, and conclusions	Abstract
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Methods: Trial design ("ClinicalTrials.gov NCT05458999")
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	Methods: Trial design (Cites published protocol [Ref 16])
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	Methods: Data collection ("...stored on a restricted-access workstation")
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	Methods: Trial design ("Investigator-initiated")
	5b	Financial and other conflicts of interest of the manuscript authors	Title Page / COI Statement
Introduction			
Background and rationale	6	Scientific background and rationale	Introduction (Last paragraph: "The ReViCTO trial was designed to test...")
Objectives	7	Specific objectives related to benefits and harms	Introduction (Last paragraph: "The ReViCTO trial was designed to test...")
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	N/A
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover),	Methods: Trial design ("...randomized, controlled,

		allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	open-label, superiority trial...", "1:1 ratio")
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	N/A (No major changes reported)
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	Methods: Participants ("Hospital Clínico Universitario de València")
Eligibility criteria	12a	Eligibility criteria for participants	Methods: Participants (Age >18, elective CTO PCI, exclusions)
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	N/A
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	Methods: Interventions (VR: Netflix "Our Planet"; Control: Usual care)
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	Methods: Outcomes (Primary: VASa; Secondary: VASp, drugs, satisfaction)
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	Methods: Data collection ("...recorded... nausea, dizziness")
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	Methods: Sample size estimation (N=58, Delta=2, SD=2.7, Power=80%)

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	16b	Explanation of any interim analyses and stopping guidelines	N/A (No interim analyses reported)
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	Methods: Randomization ("computer-generated permuted blocks")
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	Methods: Randomization ("permuted blocks")
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	Methods: Randomization ("web-based application... preventing modification")
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Methods: Randomization ("...assigned treatment arm after enrollment")
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	Methods: Randomization ("No blinding was applied")
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	N/A (Open label)
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Methods: Statistical analysis (t-test, Mann-Whitney U, Fisher's exact)
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	Results: Primary endpoint ("...available for all randomized participants")
	21c	How missing data were handled in the analysis	Implied Complete Case (Available for all randomized)
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses),	Methods: Statistical analysis (ANCOVA for baseline;

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		distinguishing prespecified from post hoc	Multivariable regression for J-CTO)
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	Results: Patients & Figure 1
	22b	For each group, losses and exclusions after randomisation, together with reasons	Results: Patients & Figure 1
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Results: Patients ("1 March 2022 to 23 Oct 2025")
	23b	If relevant, why the trial ended or was stopped	N/A
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	Results: Safety and acceptability (Discontinuation details reported)
	24b	Concomitant care received during the trial for each group	Results: Secondary endpoints (Morphine/Midazolam use reported)
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Results: Baseline characteristics & Table 1
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results: Primary endpoint & Table 2 (Mean diff, 95% CI reported)

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		● for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	Results: Safety and acceptability (Nausea: 1, Dizziness: 1)
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	Results: Primary endpoint (Adjusted analyses for J-CTO and drugs detailed here & Supplementary Table 1)
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Discussion ("...VR did not meaningfully reduce... anxiety...")
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	Discussion: Limitations (Addressed J-CTO imbalance, open-label, etc.)

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123